

AMENDED IN SENATE APRIL 21, 2003

SENATE BILL

No. 322

Introduced by Senator Ortiz

February 19, 2003

An act to add ~~Section 125118~~ *Sections 125118, 125119, 125120, 125121, and 125122* to the Health and Safety Code, relating to medical research.

LEGISLATIVE COUNSEL'S DIGEST

SB 322, as amended, Ortiz. Stem cell research proposals.

Existing law states the policy of the state that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including somatic cell nuclear transplantation, shall be permitted and that full consideration of the ethical and medical implications of this research be given, and that research involving the derivation and use of these cells shall be reviewed by an approved institutional review board.

This bill would require the *Director of the State Department of Health Services* to establish ~~the Stem Cell Institutional Review Board~~ *a Human Stem Cell Review Council*, to be comprised of *specified* members ~~selected by the department, to review and approve proposals for stem cell research projects.~~ *This bill would require the council to develop guidelines for research involving the derivation or use of human stem cells in the state. The bill would provide that it is unprofessional conduct for any licensed health care provider to conduct research concerning human stem cells in a manner that does not comply with these guidelines. The bill would authorize the council to take specified actions if the council determines that a researcher is conducting research in a manner that is in conflict with the guidelines.*

This bill would also impose specified reporting requirements on principal investigators conducting research projects concerning the derivation or use of human stem cells. The bill would require all research projects concerning this topic to be reviewed and approved by a federally approved institutional review board.

This bill would also require the council to report annually to the director and the Legislature concerning its activities.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 ~~SECTION 1.—Section 125118 is added to the Health and~~
2 SECTION 1. (a) *The Legislature finds and declares all of the*
3 *following:*
4 (1) *Isolation of human stem cells represents a major step*
5 *forward in human biology and has generated much interest among*
6 *scientists and the public, particularly among patients and their*
7 *advocates regarding the benefits of human stem cells and stem cell*
8 *research.*
9 (2) *Because human stem cells can give rise to many different*
10 *types of cells, such as muscle cells, nerve cells, heart cells, and*
11 *others, they are enormously important to science and hold great*
12 *promise for advances in health care.*
13 (3) *Research using human stem cells may help scientists*
14 *generate cells and tissue that could be used for transplantation and*
15 *may someday be used as replacement cells and tissue to treat many*
16 *diseases and conditions, including Parkinson's disease, spinal*
17 *injury, stroke, burns, heart disease, diabetes, and arthritis.*
18 (4) *Research involving human stem cells may also improve*
19 *understanding of the complex events that occur during normal*
20 *human development and what causes diseases and conditions*
21 *including birth defects and cancer, and may improve the way new*
22 *drugs are developed and tested for safety and efficacy.*
23 (5) *In view of the scientific and medical benefits that may result*
24 *from research using human stem cells, it is essential that this*
25 *research be supported and encouraged. However, in view of the*
26 *ethical, legal, and social issues relevant to human stem cell*
27 *research, it is essential that this research be subjected to oversight*

1 *more stringent than that associated with the traditional National*
2 *Institutes of Health scientific peer review process.*

3 *(6) The National Institutes of Health currently has no*
4 *comprehensive guidelines concerning the ethical, legal, and social*
5 *issues involved with the derivation and use of human stem cells in*
6 *medical research.*

7 *(b) Therefore, it is the intent of the Legislature to establish a*
8 *state entity to develop guidelines for human stem cell research in*
9 *California and to review research projects involving the derivation*
10 *or use of human stem cells to ensure that these projects are*
11 *conducted in an appropriate manner and comply with ethical and*
12 *legal standards.*

13 *SEC. 2. Section 125118 is added to the Health and Safety*
14 *Code, to read:*

15 *125118. (a) The director shall establish a Human Stem Cell*
16 *Research Review Council.*

17 *(b) The council shall consist of 13 members, comprised as*
18 *follows:*

19 *(1) Seven scientists with experience in biomedical research in*
20 *the fields of cell differentiation, nuclear reprogramming, tissue*
21 *formation and regeneration, stem cell biology, developmental*
22 *biology, regenerative medicine, or related fields, who are not*
23 *currently conducting, and have no plans to conduct, research*
24 *involving human stem cells.*

25 *(2) Two medical ethicists.*

26 *(3) Two persons with backgrounds in legal issues involved with*
27 *human stem cell research, in vitro fertilization, or family law as it*
28 *applies to donation of embryos and oocytes.*

29 *(4) Two persons who are members or leaders of religious*
30 *organizations.*

31 *SEC. 3. Section 125119 is added to the Health and Safety*
32 *Code, to read:*

33 *125119. (a) The council shall develop guidelines for research*
34 *involving the derivation or use of human stem cells in California*
35 *and for review of research projects involving the derivation or use*
36 *of human stem cells in California.*

37 *(b) In developing the guidelines specified in subdivision (a),*
38 *the council may consider other applicable guidelines developed or*
39 *in use in the United States and in other countries, including, but*
40 *not limited to, the Guidelines for Research Using Human*

1 *Pluripotent Stem Cells developed by the National Institutes of*
2 *Health and published in August 2000, and corrected in November*
3 *2000.*

4 *SEC. 4. Section 125120 is added to the Health and Safety*
5 *Code, to read:*

6 *125120. All research projects involving the derivation or use*
7 *of human stem cells shall be reviewed and approved by a federally*
8 *approved institutional review board prior to being undertaken.*
9 *Any federally approved institutional review board shall ensure that*
10 *any project that it reviews meets and complies with the guidelines*
11 *developed by the council pursuant to Section 125119.*

12 *SEC. 5. Section 125121 is added to the Health and Safety*
13 *Code, to read:*

14 *125121. (a) The principal investigator in any research*
15 *project involving the derivation or use of human stem cells that has*
16 *been reviewed and approved by a federally approved institutional*
17 *review board shall submit, or cause to be submitted, to the council*
18 *established pursuant to Section 125118, on a timetable to be*
19 *established by the council, progress reports on the research that*
20 *are sufficient to enable the council to determine that the research*
21 *continues to comply with the guidelines established by the council.*

22 *(b) The conduct of research involving the derivation or use of*
23 *human stem cells in a manner that does not comply with the*
24 *guidelines established pursuant to Section 125119 by any licensed*
25 *health care provider shall constitute unprofessional conduct.*

26 *(c) If the council determines that a researcher is conducting*
27 *research in a manner in conflict with the guidelines established*
28 *pursuant to Section 125119, it may take any of the following*
29 *actions:*

30 *(1) Request a modification in the research plan or design.*

31 *(2) Request that the research be discontinued.*

32 *(3) Request that funding for the research be discontinued.*

33 *(4) Refer any investigator or principal to an appropriate*
34 *licensing board.*

35 *(5) Refer the conduct to any law enforcement body, if*
36 *appropriate.*

37 *SEC. 6. Section 125122 is added to the Health and Safety*
38 *Code, to read:*

39 *125122. The council shall report annually to the director and*
40 *the Legislature on its actions, including the number of research*

1 *projects that it has reviewed and the status and disposition of those*
2 *projects.*

3 ~~Safety Code, to read:~~

4 ~~125118. (a) There is hereby established in the State~~
5 ~~Department of Health Services the Stem Cell Institutional Review~~
6 ~~Board.~~

7 ~~(b) The membership of the board shall be comprised of~~
8 ~~members selected by the department.~~

9 ~~(c) The purpose of the board is to review and approve proposals~~
10 ~~for stem cell research projects.~~

